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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,415	09/28/2001	Ibraheem Badejo	108773	1494

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EXAMINER
PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
	1654

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/964,415	Applicant(s) Badejo, I.
Examiner Patricia Patten	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Mar 6, 2003

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-66 is/are pending in the application.

4a) Of the above, claim(s) 7-17 and 32-66 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-6 and 18-31 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>4</u>	6) <input type="checkbox"/> Other: _____

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DETAILED ACTION

Claims 1-66 are pending in the application.

Applicant's election with traverse of Group I, Claims 1-31 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the Examiner has not established that a serious burden of search would be required (p.2, Arguments). This is not found persuasive because, as indicated in the Restriction requirement dated 2/17/02 (Paper No.6), it was clearly established that the search for each of the inventions would not be co-extensive, particularly regarding the non-patented literature. It was further pointed out that as evidenced by the claims themselves, the method for using the product may be carried out by numerous additives and therefore a search for the product may not necessarily unfold the method for using which would incorporate the need for a separate burdensome search.

The requirement is still deemed proper and is therefore made FINAL. Claims 32-66 have been withdrawn from further consideration on the merits as being drawn to a non-elected invention.

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It has been made clear from a Telephone conversation with Attorney Joel Armstrong that Applicants wish to elect 'plant extracts' as the species, and 'tetrahydrocurcumin' as the sub-species.

The species 'tetrahydrocurcumin' was not found. Therefore, the Examiner has chosen another sub-species for examination on the merits: grape extract and grape skin extract (these were examined together because the Examiner found 'tannic acid' which is found in grapes as well as grape skins).

Because claims 7-17 are drawn to the non-elected species and/or sub-species, these claims have been withdrawn from further consideration on the merits as being drawn to a non-elected invention.

Claims 1-6 and 18-31 were examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 18-21, 24, 25, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyami (US 3,507,822).

Miyami (US 3,507,822) disclosed a composition suitable for coating teeth and sealing wounds (col.2, lines 34-46) via use of a composition comprising ethyl cyanoacrylate (an α -cyanoacrylate), tannic acid (stabilizer, extract found in grapes/grape skin), fluoride (a non-stabilizing/medicinal agent), benzyl butyl phthalate (plasticizer) (Please see Example 3 as displayed below).

EXAMPLE 3	
Tooth coating:	Parts
Vinyl resin solution (40% solution of copolymer of 60% vinyl chloride, 30% vinyl acetate and 10% methyl methacrylate in ethyl and butyl acetate and methyl ethyl ketone)	100
Benzyl butyl phthalate	30
Ethyl cyanoacrylate	0.4
Tannic acid	0.2
Tin fluoride	0.1

Here, it is clear that the tannic acid stabilizer was present at 0.2 parts, or 0.2% of the composition, thereby satisfying the requirements of Instant claims 20 and 21.

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It is deemed that the stabilizer was present in this composition in an effective amount to provide wound healing since Miyami specifically stated that the compositions of his invention were used for "...suture material in cutting blood vessels, gullet or trachea in surgical operation when it is used for organs of the human body" (col.2, lines 40-43).

It is further deemed that tannic acid is oil soluble considering it's four phenyl groups.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyami (US 3,507,822). Claims 22 and 23 are drawn to wherein the composition has a Sterility Assurance Level of not better than 10^{-3} and wherein the composition is sterilized to a Sterility Assurance Level of at least 10^{-3} . Claim 26 is

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drawn to wherein the stabilizer is present in an amount sufficient to stabilize the composition during sterilization. Claim 27 is drawn to wherein the stabilizer is present in an amount sufficient to stabilize said composition during and subsequent to sterilization.

The teachings of Miyami were discussed *supra*. Miyami did not explicitly teach wherein the amount of tannic acid was chosen to stabilize the composition during and subsequent to sterilization. Nor did Miyami discuss wherein the composition had a Sterility Assurance Level of not better than 10^{-3} or wherein the composition is sterilized to a Sterility Assurance Level of at least 10^{-3} .

Miyami did particularly teach that sterilizing agents were advantageously combined with the composition if being used for medical purposes (col.3, lines 57-60).

One of ordinary skill in the art would have had a reasonable expectation that the stabilizing agent was in a sufficient amount to sustain the addition of a stabilizer since Miyami specifically suggested the incorporation of a stabilizer. Although Miyami did not specifically mention where the composition was sterilized to any particular range, the ordinary artisan would have been motivated to have sterilized the composition to the

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particularly claimed sterility assurance levels for treating internal wounds which were highly susceptible to infection.

Claims 1-6 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyami (US 3,507,822) in view of Papay (US 5,866,106). Claims 29-31 are drawn to wherein the composition of the Instant invention further comprises an antioxidant stabilizer. Claim 31 particularly recites wherein the antioxidant stabilizer is pentamethylchromanol.

The teachings of Miyami (US 3,507,822) were discussed *supra*. Miyami did not specifically teach wherein the composition further comprised an antioxidant stabilizer.

Papay (US 5,866,106) taught that antioxidants were advantageously added to compositions comprising cyanoacrylates in order to inhibit free radical formation which may have led to cancer (col.1, lines 12-21 and col.2, lines 15-32).

One of ordinary skill in the art would have been motivated to add an antioxidant to a bonding formulation comprising cyanoacrylates in order to inhibit the formation of free radicals, thereby decreasing the patient's risk of abnormal cell proliferation.

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It is deemed that the choice of antioxidant would have been routine optimization of a result effective variable. In the instant case, because pentamethylchromanol was known in the art as an antioxidant, it is deemed that pentamethylchromanol was an obvious substitution and would have acted similarly to other antioxidants such as vitamin C or selenium, especially absent sufficient evidence to the contrary.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Patricia Dattu
5/27/03